# Appendix A

MICHAEL BILIRAKIS, FLORIDA
JOE BARTON, TEXAS
FRED UPTON, MICHIGAN
CLIFE STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
JAMES C. GREENWOOD, PENNSYLVANIA
CHRISTOPHER COX. CALIFORNIA
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RICHARD BURR, NORTH CAROLINA
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BARBARA CUBIN, WYOMING
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN ST. STENSIEL
TORONO
CHARLES TORONO
CONTROL
TON DAVIS, VIRGINIA
ED BRYANT, TENNESSEE
ROBERT L. EHRLICH, JP., MARYLAND
STEVE BUYER, INDIANA
GEORGE RADANOVICH, CALIFORNIA
CHARLES F. BASS NEW HAMPSHIPE
JOSEPH R. PITTS, PENNSYLVANIA
MARY BONC, CALIFORNIA
GREG WALDEN, NEBRASKA

ONE HUNDRED SEVENTH CONGRESS

# U.S. House of Representatives Committee on Energy and Commerce Washington, DC 20515-6115

W.J. "BILLY" TAUZIN, LOUISIANA, CHAIRMAN

January 18, 2002

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HENRY A WAXMAN CALIFORNIA
EDWARD J MARKEY MASSACHUSETTS
RALPH M HALL TEXAS
RICK BOUCHER VIRGINIA
EDOLPHUS TOWNS NEW YORK
FRANK PALLONE UP NEW JERSEN
SHEPROD BROWN OHO
BART GORDON TENNESSEE
PETER DEUTSCH FLORIDA
BOBBY RISH ILLING S
ANNA G ESHOO CAL FORNIA
BART STUPAK MOT SAN
EUCT J ENGEL NEW YORK
TOM SAWVER OHO
ALBERT R WYNN MARYLAND
GENE GREEN TEXAS
KAREN MICHAPHY MISSOLR
TEL STRICKLAND OHO
CANA DIEGETTE COLORADO
THOMAS M BARRETT WISCONSIN
BLILL THER MINNESCTA
LC S CAPPS CALIFORNIA
MICHAEL FOOLLE PENNINEVANIA
CHEST CHER MON

DAVID VIMARVENTANCI STAFF DIRECTOR

Mr. Peter Dolan Chairman and Chief Executive Officer Bristol-Myers Squibb World Headquarters 345 Park Avenue New York, New York 10154-0037

Dear Mr. Dolan:

The Subcommittee on Oversight and Investigations is investigating questions about the conduct of ImClone Systems, Inc. in the development of its colorectal cancer drug, Erbitux (also known as C225 or Cetuximab).

ImClone Systems and Erbitux are internationally known, having been featured on the CBS program "60 Minutes" and the international cover story for the July 30, 2001 issue of Business Week. One reason Erbitux received such attention is that, according to Business Week, this drug was "the furthest along of a handful of new cancer treatments that precisely home in on a growth signal found in up to 50% of all cancer types." In clinical trials, "the drug demonstrated remarkable success in causing colon cancer to regress in patients who had failed to respond to all other treatments." Such promise apparently prompted thousands of cancer patients to try to obtain Erbitux either through clinical trial enrollment or "compassionate use" access. For example, USA Today reported that ImClone had received 400 calls a day from patients desperate to get Erbitux outside clinical trials.

In September 2001, Bristol-Myers Squibb bought 20 percent of ImClone for \$1 billion and agreed to pay as much as \$1 billion more to obtain the marketing rights to Erbitux. On October 30, 2001, ImClone submitted its biologics license application for Erbitux. On December 17, 2001, ImClone was one of seven biotechnology companies included for the first time in the NASDAQ 100 index. Excitement and confidence in ImClone was reflected in such media reports as a Reuters article in the December 26, 2001 Los Angeles Times which proclaimed, "Erbitux, a colon cancer treatment from ImClone Systems Inc., is set to make one of the biggest splashes of 2002."

Therefore, many observers were stunned to learn that on December 28, 2001, the FDA had issued a "refuse-to-file" (RTF) letter in response to the ImClone submission. The RTF letter, sent in rare cases when a submission is deemed insufficient, is a non-public document containing trade secret or confidential commercial information. According to Adam Feuerstein's column in TheStreet.com, in "its December 31, 2001 conference call, ImClone executives said that FDA regulators sent the RTF letter because the Erbitux application was missing certain 'train of documentation' information needed by regulators to accept the filing. ImClone said it would be able to answer the FDA questions by the end of the first quarter, leading, hopefully to an approval of Erbitux in the fall." On the first trading day after the issuance of the RTF letter, ImClone's shares fell \$11.15, or 20% to \$44.10 per share.

On January 4, 2002, the Cancer Letter published excerpts of the RTF letter indicating that the FDA had greater concerns about ImClone's data than company executives stated in the December 31st conference call with analysts and investors. As Adam Feuerstein noted, "if the Cancer Letter does have a correct copy of the RTF letter, it suggests that ImClone executives have not given investors and Wall Street analysts a full picture of the Erbitux problems." The Cancer Letter article reported that the RTF letter detailed a long list of FDA concerns that went far beyond record keeping. The FDA was quoted as saving that ImClone's clinical trial was "not adequate and well controlled" and that additional studies would be needed. Moreover, the letter suggested that the FDA had warned ImClone starting in August 2000 that its data would have to demonstrate that Campostar, another cancer drug, was needed along with Erbitux. But the data submitted by ImClone was not sufficient to distinguish the effects of Campostar and Erbitux. Furthermore, the FDA cited protocol violations in the clinical trial, specifically the fact that ImClone only reported the deaths of three patients who died within a month of their last Erbitux treatment. The FDA found 21 patients who died within a month of their last Erbitux treatment. According to the January 8, 2002 New York Times, David Hines, president of the Avalon Research Group, said, "The FDA's communications with the company appear directly at odds with the statements made by the company in 2001." After the Cancer Letter report appeared, the price of ImClone shares fell further to open on January 7, 2002 at \$34.96 per share.

On January 9, 2002, after ImClone had lost nearly \$1.5 billion in market value since December 28 and after the filing of at least 11 federal class action suits, Sam Waksal, the ImClone president and CEO, attempted to explain the company's situation at the J.P. Morgan H&Q Healthcare conference. "What happened was that we put together a faulty package and we screwed up," Waksal reportedly said. The principal problem, he said, was the company's failure to provide documentation demonstrating that the patients enrolled in ImClone's pivotal trial had met the eligibility criteria. On January 11, 2002, the Cancer Letter published an article on the conference and raised more questions about Waksal's explanations of what went wrong. For example, Waksal said that the problems were caused by the Independent Response Assessment Committee (IRAC), a group of two radiologists and two oncologists who reviewed the data from the trial's sites. However, the Cancer Letter article cites Howard Ozer, director of Oklahoma University Cancer Center and Eason chair of oncology and hematology, who said blaming the review committee is disingenuous. "It is not the IRAC's fault," said Ozer, who reviewed the

Mr. Peter Dolan Page 3

RTF letter for The Cancer Letter. "IRAC would have done whatever they were asked to do." The committee was working for the company, which means that the company bears the ultimate responsibility, Ozer said. "They would know when IRAC is screwing up, and they would immediately report back," Ozer said. "Companies do it in self-defense, so this kind of thing doesn't happen."

Adding to the controversy are sales of stock by ImClone executives in the weeks just before FDA issued the RTF letter. According to the January 9, 2002 Wall Street Journal, ImClone's Chief Operating Officer, Harlan Waksal, disposed of 700,000 ImClone shares on December 6, valued at roughly \$71 a share or about \$50 million in total. On October 29, 2001, ImClone executives and directors sold a combined 2.1 million company shares to Bristol-Myers for \$150 million. Samuel Waksal sold 814,674 shares and Harlan Waksal sold 776,450 shares. or just more than 20% of each of their holdings, in the first sale by either executive since the mid-1990's. The sales were part of a tender offer by Bristol-Myers at the end of October in connection with the strategic agreement with ImClone. (In contrast to the \$2 billion agreement with Bristol-Myers for the US market, we note that it appears ImClone made only a \$60 million agreement with Merck KGaA for the right to market Erbitux outside North America and Japan, according to ImClone's 10-Q SEC filing). As part of the tender offer, the Waksals and other insiders – along with all other shareholders – were allowed to tender shares. However, according to the Wall Street Journal, ImClone lent money to insiders so they could acquire shares through the exercise of options at a time when discussions with Bristol-Myers "were well under way (having started in May) but weren't publicly disclosed." Along with the Waksals, ImClone extended loans to the company's chairman and another director, totaling \$35.2 million during - July and August. As one observer noted in the Wall Street Journal article, that select insiders were able to borrow money from the company in order to acquire shares "puts shareholders at a disadvantage."

Given these recent reports, we have several serious concerns. Available information seems to conflict with ImClone's descriptions of the contents of FDA's RTF letter and its clinical research. The RTF letter is not a public document; investors only learned about the details from the excerpts of the RTF letter reported in the Cancer Letter. Without the Cancer Letter article, investors would have had to rely on ImClone's questionable descriptions of the RTF letter.

We are also interested in learning about the true nature of the pivotal clinical trial for Erbitux, and whether ImClone knew or should have known about the insufficiencies detailed in FDA's RTF letter. It is important that the hopes of cancer patients are not falsely raised and that the integrity of biomedical research is maintained. The available information demands that this Committee, which is entrusted with the oversight of public health and consumer protection laws, get additional information about ImClone and the Erbitux matter.

In light of these concerns, pursuant to Rules X and XI of the U.S. House of Representatives, please provide the following by January 31, 2002:

- 1. All records relating to communications about the FDA's December 28, 2001 refusal-to-file letter regarding ImClone's Erbitux.
- 2. A list of the individuals involved in Bristol-Myers Squibb's (BMS) due diligence review of ImClone Systems. Please describe how BMS organized its due diligence efforts regarding ImClone Systems.
- 3. Internal audits, internal investigations, and/or reports relating to ImClone Systems.
- 4. Did BMS draw on the expertise of its Oncology Advisory Board to assess the Erbitux data before the ImClone deal was completed? If not, why not? What information did BMS rely on in assessing the Erbitux data?
- 5. All records relating to the October 26, 2001 briefing before the BMS Oncology Advisory Board concerning Erbitux.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. In addition, we are requesting that following production of the records to the Committee, you make available Bristol-Myers Squibb employees for Committee staff interviews as requested by Committee staff.

Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-2927.

Sincerely,

W.J. "BILLY" TAUZIN CHAIRMAN

JAMES C. GREENWOOI

CHAIRMAN

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

cc:

The Honorable John D. Dingell, Ranking Minority Member The Honorable Peter Deutsch, Ranking Minority Member Subcommittee on Oversight and Investigations

Attachment

### ATTACHMENT

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- 2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

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ALBERT E WANN MARNIAN'
GENE BREEK TEXAS
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DAVID C MARKENTANC STARK LIRECTOR

Dr. Bernard Schwetz, D.V.M., Ph.D. Acting Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

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Dr. Bernard Schwetz, D.V.M., Ph.D. Page 2

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Dr. Bernard Schwetz, D.V.M., Ph.D. Page 3

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Given these recent reports, we have several serious concerns. Available information seems to conflict with ImClone's descriptions of the contents of FDA's RTF letter and its clinical research. The RTF letter is not a public document; investors only learned about the details from the excerpts of the RTF letter reported in the Cancer Letter. Without the Cancer Letter article, investors would have had to rely on ImClone's questionable descriptions of the RTF letter. The FDA's statute and regulations appear to inhibit the agency on its own from disclosing some, if not all, of the RTF letter or other similar, relevant information to the Securities and Exchange Commission (SEC) when there are concerns about the accuracy and completeness of company's descriptions of FDA actions. We note that Section 301(i) of the Federal Food, Drug, and Cosmetic Act prohibits the "revealing, other than to the Secretary or officers or employees of the Department . . . any information . . . concerning any method or process which as a trade secret is entitled to protection." Therefore, according to FDA's Regulatory Procedures Manual, FDA may not share trade secret information with federal government agencies outside the Department of Health and Human Services unless the submitter of the trade secret consents in writing. Under 21 C.F.R. section 20.85 any FDA records exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited from disclosure by 21 USC 331(j) . . . may be released only as provided by these sections. For the

Dr. Bernard Schwetz, D.V.M., Ph.D. Page 4

-sake of protecting patients and investors from deception, we are interested in learning whether FDA laws need to be clarified to permit the FDA on its own accord, and in appropriate circumstances, to share non-public information with other federal agencies.

We are also interested in learning about the true nature of the pivotal clinical trial for Erbitux, and whether ImClone knew or should have known about the insufficiencies detailed in FDA's RTF letter. It is important that the hopes of cancer patients are not falsely raised and that the integrity of biomedical research is maintained. The available information demands that this Committee, which is entrusted with the oversight of public health and consumer protection laws, get additional information about ImClone and the Erbitux matter.

In light of these concerns, pursuant to Rules X and XI of the U.S. House of Representatives, please provide the following by January 31, 2002:

- 1. All records relating to the December 28, 2001 refusal-to-file letter for ImClone Systems' biological license application for Erbitux.
- 2. All records relating to meetings between FDA and ImClone Systems concerning Erbitux.
- 3. All records relating to study CP02-9923, especially the study protocol.
- 4. All records relating to communications about the biological license application for Erbitux since October 29, 2001.
- 5. The most current legal analysis of relevant federal statutes and regulations concerning FDA disclosure of non-public information to the Securities and Exchange Commission (SEC). If no such analysis exists, please provide an explanation to the Committee of the circumstances, and for what categories of non-public information, that FDA on its own initiative may provide to the SEC. Please advise the Committee on whether FDA has had contact with the SEC on the ImClone/Erbitux matter and, if there was contact, appropriate details about the nature of the contact.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. In addition, we are requesting that following production of the records to the Committee, you make available FDA employees for Committee staff interviews as requested by Committee staff.

Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-2927.

Dr. Bernard Schwetz, D.V.M., Ph.D. Page 5

Sincerely,

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

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The Honorable John D. Dingell, Ranking Minority Member The Honorable Peter Deutsch, Ranking Minority Member Subcommittee on Oversight and Investigations

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DAVID V MARVENTANO STAFF DIRECTOR

Dr. Samuel Waksal President and Chief Executive Officer ImClone Systems, Inc. 180 Varick Street New York, New York 10014

Dear Dr. Waksal:

The Subcommittee on Oversight and Investigations is investigating questions about the conduct of ImClone Systems. Inc. in the development of its colorectal cancer drug, Erbitux (also known as C225 or Cetuximab).

ImClone Systems and Erbitux are internationally known, having been featured on the CBS program "60 Minutes" and the international cover story for the July 30, 2001 issue of Business Week. One reason Erbitux received such attention is that, according to Business Week, this drug was "the furthest along of a handful of new cancer treatments that precisely home in on a growth signal found in up to 50% of all cancer types." In clinical trials, "the drug demonstrated remarkable success in causing colon cancer to regress in patients who had failed to respond to all other treatments." Such promise apparently prompted thousands of cancer patients to try to obtain Erbitux either through clinical trial enrollment or "compassionate use" access. For example, USA Today reported that ImClone had received 400 calls a day from patients desperate to get Erbitux outside clinical trials.

In September 2001, Bristol-Myers Squibb bought 20 percent of ImClone for \$1 billion and agreed to pay as much as \$1 billion more to obtain the marketing rights to Erbitux. On October 30, 2001, ImClone submitted its biologics license application for Erbitux. On December 17, 2001, ImClone was one of seven biotechnology companies included for the first time in the NASDAQ 100 index. Excitement and confidence in ImClone was reflected in such media reports as a Reuters article in the December 26, 2001 Los Angeles Times which proclaimed, "Erbitux, a colon cancer treatment from ImClone Systems Inc., is set to make one of the biggest splashes of 2002."

Therefore, many observers were stunned to learn that on December 28, 2001, the FDA had issued a "refuse-to-file" (RTF) letter in response to the ImClone submission. The RTF

letter, sent in rare cases when a submission is deemed insufficient, is a non-public document containing trade secret or confidential commercial information. According to Adam Feuerstein's column in TheStreet.com, in "its December 31, 2001 conference call, ImClone executives said that FDA regulators sent the RTF letter because the Erbitux application was missing certain 'train of documentation' information needed by regulators to accept the filing. ImClone said it would be able to answer the FDA questions by the end of the first quarter, leading, hopefully to an approval of Erbitux in the fall." On the first trading day after the issuance of the RTF letter, ImClone's shares fell \$11.15, or 20% to \$44.10 per share.

On January 4, 2002, the Cancer Letter published excerpts of the RTF letter indicating that the FDA had greater concerns about ImClone's data than company executives stated in the December 31st conference call with analysts and investors. As Adam Feuerstein noted, "if the Cancer Letter does have a correct copy of the RTF letter, it suggests that ImClone executives have not given investors and Wall Street analysts a full picture of the Erbitux problems." The Cancer Letter article reported that the RTF letter detailed a long list of FDA concerns that went far beyond record keeping. The FDA was quoted as saying that ImClone's clinical trial was "not adequate and well controlled" and that additional studies would be needed. Moreover, the letter suggested that the FDA had warned ImClone starting in August 2000 that its data would have to demonstrate that Campostar, another cancer drug, was needed along with Erbitux. But the data submitted by ImClone was not sufficient to distinguish the effects of Campostar and Erbitux. Furthermore, the FDA cited protocol violations in the clinical trial, specifically the fact that ImClone only reported the deaths of three patients who died within a month of their last Erbitux treatment. The FDA found 21 patients who died within a month of their last Erbitux treatment. According to the January 8, 2002 New York Times, David Hines, president of the Avalon Research Group, said, "The FDA's communications with the company appear directly at odds with the statements made by the company in 2001." After the Cancer Letter report appeared, the price of ImClone shares fell further to open on January 7, 2002 at \$34.96 per share.

On January 9, 2002, after ImClone had lost nearly \$1.5 billion in market value since December 28 and after the filing of at least 11 federal class action suits, you attempted to explain the company's situation at the J.P. Morgan H&Q Healthcare conference. "What happened was that we put together a faulty package and we screwed up," you reportedly said. The principal problem, you said, was the company's failure to provide documentation demonstrating that the patients enrolled in ImClone's pivotal trial had met the eligibility criteria. On January 11, 2002, the Cancer Letter published an article on the conference and raised more questions about your explanations of what went wrong. For example, you said that the problems were caused by the Independent Response Assessment Committee (IRAC), a group of two radiologists and two oncologists who reviewed the data from the trial's sites. However, the Cancer Letter article cites Howard Ozer, director of Oklahoma University Cancer Center and Eason chair of oncology and hematology, who said blaming the review committee is disingenuous. "It is not the IRAC's fault," said Ozer, who reviewed the RTF letter for The Cancer Letter. "IRAC would have done whatever they were asked to do." The committee was working for the company, which means that the company bears the ultimate responsibility, Ozer said. "They would know when IRAC is

screwing up, and they would immediately report back." Ozer said. "Companies do it in self-defense, so this kind of thing doesn't happen."

Adding to the controversy are sales of stock by ImClone executives in the weeks just before FDA issued the RTF letter. According to the January 9, 2002 Wall Street Journal. ImClone's Chief Operating Officer, Harlan Waksal, disposed of 700,000 ImClone shares on December 6, valued at roughly \$71 a share or about \$50 million in total. On October 29, 2001, ImClone executives and directors sold a combined 2.1 million company shares to Bristol-Myers for \$150 million. You sold 814,674 shares and Harlan Waksal sold 776,450 shares, or just more than 20% of each of their holdings, in the first sale by either you or your brother since the mid-1990's. The sales were part of a tender offer by Bristol-Myers at the end of October in connection with the strategic agreement with ImClone. (In contrast to the \$ 2 billion agreement with Bristol-Myers for the US market, we note that it appears ImClone made only a \$60 million agreement with Merck KGaA for the right to market Erbitux outside North America and Japan, according to ImClone's 10-Q SEC filing). As part of the tender offer, you and your brother and other insiders - along with all other shareholders - were allowed to tender shares. However, according to the Wall Street Journal, ImClone lent money to insiders so they could acquire shares through the exercise of options at a time when discussions with Bristol-Myers "were well under way (having started in May) but weren't publicly disclosed." Along with you and your brother, ImClone extended loans to the company's chairman and another director, totaling \$35.2 million during July and August. As one observer noted in the Wall Street Journal article, that select insiders were able to borrow money from the company in order to acquire shares "puts shareholders at a disadvantage."

Given these recent reports, we have several serious concerns. Available information seems to conflict with ImClone's descriptions of the contents of FDA's RTF letter and its clinical research. The RTF letter is not a public document; investors only learned about the details from the excerpts of the RTF letter reported in the Cancer Letter. Without the Cancer Letter article, investors would have had to rely on ImClone's questionable descriptions of the RTF letter.

We are also interested in learning about the true nature of the pivotal clinical trial for Erbitux, and whether ImClone knew or should have known about the insufficiencies detailed in FDA's RTF letter. It is important that the hopes of cancer patients are not falsely raised and that the integrity of biomedical research is maintained. The available information demands that this Committee, which is entrusted with the oversight of public health and consumer protection laws, get additional information about ImClone and the Erbitux matter.

In light of these concerns, pursuant to Rules X and XI of the U.S. House of Representatives, please provide the following by January 31, 2002:

1. All records relating to communications about the FDA's December 28, 2001 refusal-to-file letter.

- 2. All records relating to meetings between FDA and ImClone Systems concerning Erbitux.
- 3. All records relating to study CP02-9923, especially the study protocol. Please identify the ImClone official responsible for coordinating with the Independent Response Assessment Committee. Please provide a list of all outside consultants or experts used by ImClone for study CP02-9923.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. In addition, we are requesting that following production of the records to the Committee, you make yourself available, as well as ImClone employees for Committee staff interviews as requested by Committee staff.

Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-2927.

Sincerely,

W.J. "BILLY" TAUZIN

CHAIRMAN<sup>®</sup>

AMES C. GREENWOOD

CHAIRMAN

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

cc: The Honorable John D. Dingell, Ranking Minority Member The Honorable Peter Deutsch, Ranking Minority Member Subcommittee on Oversight and Investigations

Attachment

#### **ATTACHMENT**

- 1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements. drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intraoffice and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
- 2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.